

**MORRISON | FOERSTER**

1290 AVENUE OF THE AMERICAS  
NEW YORK, NY 10104-0050  
TELEPHONE: 212.468.8000  
FACSIMILE: 212.468.7900  
WWW.MOFO.COM

MORRISON & FOERSTER LLP  
NEW YORK, SAN FRANCISCO,  
LOS ANGELES, PALO ALTO,  
SACRAMENTO, SAN DIEGO,  
DENVER, NORTHERN VIRGINIA,  
WASHINGTON, D.C.  
TOKYO, LONDON, BRUSSELS,  
BEIJING, SHANGHAI, HONG KONG,  
SINGAPORE

September 16, 2013

Writer's Direct Contact  
212.468.8032  
KHagberg@mofo.com

Hon. Shira A. Scheindlin  
United States District Judge  
United States District Court  
Southern District of New York  
500 Pearl Street  
New York, NY 10007-1312

**Re: *Sekisui America Corporation et al. v. Hart et al.*, Case No. 12-cv-3479 (SAS) (FM)**

Dear Judge Scheindlin:

In accordance with Your Honor's instructions during the August 26, 2013 conference, we submit the following pre-motion letter on behalf of Plaintiffs regarding Plaintiffs' proposed motions *in limine* to exclude portions of the expert reports proffered by Defendants.

Plaintiffs proffered three expert witnesses: Carrie Kuehn opined on American Diagnostica, Inc.'s ("ADI") compliance with the Food, Drug and Cosmetic Act and related regulations, Timothy Ulatowski opined on the viability of the ADI's section 510(k) submission to the FDA for premarket clearance to market a breast cancer diagnostic known as Femtelle, and Guy Erb opined on Plaintiffs' damages for Defendants' breaches of certain representations and warranties in the parties' Stock Purchase Agreement. Defendants proffered two expert witnesses solely in rebuttal: Mukesh Bajaj was offered to rebut the

MORRISON | FOERSTER

September 16, 2013  
Page Two

opinion of Guy Erb and Thomas Becze was offered to rebut the opinions of Ms. Kuehn and Mr. Ulatowski.

Plaintiffs seek to move to exclude portions of the expert reports of Dr. Bajaj and Mr. Becze for failure to comply with *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993) and Federal Rule of Evidence 702. To determine whether a proposed expert witness's testimony passes muster under *Daubert* and Rule 702, this Court must inquire into: (1) the qualifications of the proposed expert; (2) whether each proposed opinion is based upon reliable data and reliable methodology; and (3) whether the proposed testimony would be helpful to the trier of fact. *See, e.g., Nimely v. City of New York*, 414 F.3d 381, 396-97 (2d Cir. 2005). Several of the opinions offered by Defendants' experts fail to satisfy these factors.

**A. Portions of Dr. Bajaj's Opinion Should Be Excluded.**

Dr. Bajaj has offered several opinions that are unreliable and, in some cases, are beyond his expertise. Indeed, two courts in the Southern District of New York have excluded Dr. Bajaj's testimony in the last two months on those same grounds. *See SEC v. Tourre*, No. 10-Civ-3229, 2013 U.S. Dist. LEXIS 87211, at \*18-22 (S.D.N.Y. June 18, 2013) (excluding expert testimony of Dr. Bajaj on grounds he was not qualified to offer some of his opinions, some were impermissible *ipse dixit*, and some invaded the purview of the fact finder); *Bank of America v. Bear Stearns Asset Mgmt.*, No. 08-Civ-9265, 2013 U.S. Dist. LEXIS 125700, at \*15-16 (S.D.N.Y. Sept. 3, 2013) (excluding opinion of Dr. Bajaj because the methodology used was "inherently unreliable").

September 16, 2013  
Page Three

**1. Dr. Bajaj is Not Qualified to Opine on FDA Issues.**

Dr. Bajaj—a financial economist—admitted at his deposition that he is not an expert on FDA matters. (*See* Bajaj Depo. at 13:14-14:13.) His resume, education, publications and experience are devoid of any work or expertise on FDA issues, and he does not contend otherwise. Despite having no FDA expertise whatsoever, Dr. Bajaj offers two opinions on FDA matters: (1) that “it was not unusual for a 510(k) Application to face additional information requests” (*see* Bajaj Report ¶¶ 40-41); and (2) that “FDA standards got stricter [following the 510(k) submission]” (*see* Bajaj Report ¶ 72). These opinions are outside of Dr. Bajaj’s expertise and should be excluded.

**2. Dr. Bajaj is Not Qualified to Opine on the Meaning of Court Orders.**

Dr. Bajaj offers an opinion that the validity of Plaintiffs’ claims regarding Femtelle is “subject to dispute,” including because of Your Honor’s October 17, 2012 Order granting in part and denying in part Defendants’ motion to dismiss. (*See* Bajaj Report ¶¶ 17(d), 37-39.) The Court does not require expert analysis to interpret its own decisions and, even if it wanted such assistance, Dr. Bajaj is not a lawyer and is not an expert in legal matters. (*See* Bajaj Depo. at 13:8-13:13). Dr. Bajaj himself admitted that he does not “like to be in a position of characterizing a court’s opinion” (*see id.* at 18:7-8), but yet proceeds to do so in his report. This opinion is beyond Dr. Bajaj’s expertise and should be excluded.

September 16, 2013  
Page Four

3. **Dr. Bajaj Cannot Speculate that Mr. Erb Should Have Used an *Ex Ante* Valuation Approach.**

Dr. Bajaj criticizes Mr. Erb for conducting a valuation of ADI (the company that Plaintiffs purchased from Defendants) using what Dr. Bajaj terms an “*ex post*” valuation method, and that Mr. Erb should have instead used an “*ex ante*” valuation method. (See Bajaj Report ¶¶ 17(e), 53-54, 66-67.) This opinion is unreliable and speculative because, as Dr. Bajaj admitted at his deposition, he has not conducted an alternate damages analysis using an *ex ante* valuation method. (See Bajaj Depo. at 146:6-10.) Dr. Bajaj failed even to do the preliminary step of determining whether such an analysis would be feasible given the facts of this case. (See *id.* at 159:24-160:12.) Thus, Dr. Bajaj’s opinion regarding the proper valuation method in this case is wholly unreliable and speculative, and accordingly should be excluded. See *405 Condo Assocs. LLC v. Greenwich Ins. Co.*, No. 11-Civ-9662, 2012 U.S. Dist. LEXIS 181922, at \*17-18 (S.D.N.Y. Dec. 24, 2012) (excluding speculative expert testimony because “given the absence of clear methodology or relevant data” there was “simply too great an analytical gap between the data and the opinion proffered”) (citations omitted).

4. **Dr. Bajaj Should Not Be Permitted to Offer Conclusions Based on a Selective and Incorrect Reading of the Record.**

Two of Dr. Bajaj’s other opinions are based on nothing more than a recitation of the discovery record without any expert analysis. It is well settled that experts may not offer opinions on “pure questions of fact.” See *Liberty Media Corp. v. Vivendi Universal*, 874 F. Supp. 2d. 169, 178 (S.D.N.Y. 2012); *Tourre*, 2013 U.S. Dist. LEXIS 87211, at \*21

MORRISON | FOERSTER

September 16, 2013  
Page Five

(excluding Dr. Bajaj's opinions where he failed to do more than "simply assemble the record evidence and opine on what it means").

First, Dr. Bajaj opines that Defendants "paid" \$1.5 million for Femtelle. (*See* Bajaj Report ¶¶ 17(d), 39, 42, 45-46, 56.) Dr. Bajaj's report cites only to the Complaint for support of this statement, and he admitted that the \$1.5 million figure is based only on the Complaint and the draft document on which the statement in the Complaint relies. (*See* Bajaj Depo. at 129:30-130:6.) The Complaint, however, does *not* state that Plaintiffs paid \$1.5 million for Femtelle and, in fact, indicates that the parties specifically did not negotiate a separate upfront payment amount for Femtelle out of the \$25.5 million that Plaintiffs paid Defendants for ADI. (Compl. ¶ 17.) The document to which the Complaint refers, and upon which Dr. Bajaj's opinion relies, is a draft letter of intent that was not agreed to by the parties, and which was superseded by the operative letter of intent and subsequently by the signed Stock Purchase Agreement that, as noted, did not include a separate upfront payment for Femtelle. On that basis alone, Dr. Bajaj's testimony is based on unreliable data and should be excluded. *See, e.g., Santoro v. Donnelly*, 340 F. Supp. 2d. 464, 475 (S.D.N.Y. 2004) (finding expert opinion was "unreliable because it lack[ed] a sufficient factual basis"). Regardless, even if there were reliable factual support for the \$1.5 million figure, Dr. Bajaj did not calculate this number—he merely recited it based on a misreading of the Complaint and the draft letter of intent. (*See* Bajaj Depo. at 129:30-130:6.) Expert testimony is therefore not required to point the Court's attention to these documents. Dr. Bajaj's attempt

September 16, 2013  
Page Six

merely to identify a statement in the Complaint (albeit incorrectly) is not a permissible expert opinion.

Second, Dr. Bajaj opines that ADI “disclosed” up-to-date financial information to Plaintiffs prior to the acquisition. (*See* Bajaj Report ¶¶ 17(a), 18.) The basis of this opinion is a single financial document pulled from the voluminous discovery record that is date-stamped April 3, 2009 (*i.e.*, prior to the April 20, 2009 closing date). As Dr. Bajaj admitted in his deposition, he has no idea if this document was given to Plaintiffs by ADI prior to the acquisition, other than the fact that this document was produced by Plaintiffs in this litigation. (*See* Bajaj Depo. at 30:3-32:25.) Given that Plaintiffs acquired all of ADI’s pre-acquisition documents following the acquisition, the fact that Plaintiffs today possess an ADI document dated April 3, 2009 does not indicate whether such a document was provided to Plaintiffs prior to the acquisition. More importantly, it does not require expert testimony to point to this document. Dr. Bajaj conducts no analysis regarding this document. Accordingly, Dr. Bajaj’s “opinion” regarding this document should be excluded.

**B. Mr. Becze’s Opinions Rebutting Mr. Ulatowski’s Expert Opinion Should Be Excluded.**

Mr. Becze claims that Mr. Ulatowski’s opinion is “pure conjecture” because it is “impossible to predict the outcome of a 510(k) submission.” (*See* Becze Report at 6.) Mr. Becze cites to no study, does not disclose any analysis and fails to explain how any experience he has had led to this conclusion. Mr. Becze admitted at his deposition that, unlike Mr. Ulatowski, who spent 37 years at the FDA, Mr. Becze never worked at the FDA. (*See* Becze Depo. at 22:4-6.) He also admitted that there may be some circumstances when

MORRISON | FOERSTER

September 16, 2013  
Page Seven

it is apparent that a 510(k) submission is likely to fail. (*See id.* at 257:13-258:18.) He could not opine on the specific circumstances of the Femtelle 510(k) submissions because he did not read the Femtelle submissions. (*See id.* at 247:10-12.) Mr. Becze's opinion attempting to refute Mr. Ulatowski's expert opinion on the viability of the Femtelle 510(k) submission therefore lacks any reliable basis and should be excluded. *See, e.g., Grdinich v. Bradlees*, 187 F.R.D. 77, 82 (S.D.N.Y. 1999) (expert testimony inadmissible because expert based his opinion solely on his own authority); *Donnelly v. Ford Motor Co.*, 80 F. Supp. 2d 45, 49-50 (E.D.N.Y. 1999) (expert's opinion unreliable because nothing in the report explained his reasoning or methodology by which he reached his conclusions, and he did not identify any specific technique or method that he used, or cite any industry standards, surveys, or studies relied upon).

Respectfully submitted,

 (HAPN)

Karen L. Hagberg

cc: Franklin B. Velie, Esq. (fvelie@sandw.com; via ECF)  
Jonathan G. Kortmansky, Esq. (jkortmansky@sandw.com; via ECF)